



Atty. Dkt. No. 081356-0243

JPW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hiroshi MATSUI
Title: METHOD OF MULTIPLE QUANTIFICATION OF CHOLESTEROL IN
LOW-DENSITY LIPOPROTEINS
Appl. No.: 10/537,992
International Filing Date: 12/12/2003
371(c) Date: 06/09/2005
Examiner: Paul C. Martin
Art Unit: 1655
Confirmation Number: 1370

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

STATEMENT

The undersigned hereby states in accordance with 37 CFR §1.97(e)(1) that each item of information contained in this supplemental information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to filing of this Statement.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

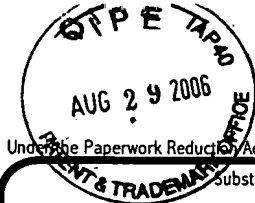
Respectfully submitted,

Date 26 August 2006

By Stephen A. Bent

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MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: August 29, 2006

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	10/537,992
Filing Date	12/12/2003
First Named Inventor	Hiroshi MATSUI
Group Art Unit	1655
Examiner Name	Paul C. Martin
Attorney Docket Number	081356-0243

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	B1	2002/015975	A1	NAKAMURA MITSUHIRO et al.	2/7/2002	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	B2	EP	0 763 741	A1	KYOWA MEDEX CO., LTD.	3/19/1997		
	B3	EP	1 197 564	A1	DAIICHI PURE CHEMICALS CO., LTD.	4/17/2002		
	B4	EP	1 164 376	A1	DAIICHI PURE CHEMICALS CO., LTD.	12/19/2001		
	B5	EP	0 887 422	A1	DENKA SEIKEN CO., LTD.	12/30/1998		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	B6	Masahiko OKADA et al., "Direct Measurement of HDL Cholesterol: Method Eliminating Apolipoprotein E-Rich Particles", Journal of Clinical Laboratory Analysis 15: 223-229 (2001).	
	B7	Y. MIKI et al., "Homogeneous assay for the selective measurement of LDL-cholesterol with polyanion and amphoteric surfactant", CLINICAL CHEMISTRY, vol. 45, no. 6, part 2, June 1999, pp. A13, XP001246917 & 51 st ANNUAL MEETING OF THE AMERICAN ASSOCIATION OF CLINICAL CHEMISTRY, NEW ORLEANS, LA, USA; JULY 25-29, 1999, ISSN: 0009-9147.	
	B8	Hiroyuki SUGIUCHI et al., "Homogeneous assay for measuring low-density lipoprotein cholesterol in serum with triblock copolymer and α -cyclodextrin sulfate", Clinical Chemistry 44:3, 522-531 (1998).	
	B9	Harry H. YU et al., "Direct Measurement of LDL-C in Children: Performance of Two Surfactant-Based Methods in a General Pediatric Population", Clinical Biochemistry, Vol. 33, No. 2, 89-95, 2000.	

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.